UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,561	10/17/2005	Mary Finbarr McSweeney	ETF-0017	3537

23413 7590 01/28/2009

CANTOR COLBURN, LLP
20 Church Street
22nd Floor
Hartford, CT 06103

EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
01/28/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

Office Action Summary	Application No.	Applicant(s)	
	10/531,561	MCSWEENEY ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are pending.

Election/Restrictions

Applicant's election with traverse of Group II, claims 1, 3-10 and 12-14 in the reply filed on 12-23-08 is acknowledged. The traversal is on the ground(s) that Groups II and V are product and method of using the product. This is found persuasive in view of the amendment. Groups II and V have been recombined. The requirement is still deemed proper and is therefore made FINAL.

Upon reconsideration, the species election has been withdrawn.

The claims are being examined as they relate to an intravascular stent having an inner surface comprising cells genetically modified to produce an enzyme capable of catabolizing cholesterol and lipids.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 is drawn to an intravascular stent comprising an inner surface having genetically modified cells that produce an enzyme capable of catabolizing cholesterol and lipids. Claim 11 is drawn to a method of using the stent to treat or prevent obstructive artheriosclerotic lesions in coronary and peripheral blood vessels, or prevent restenosis in intra coronaric stents.

Dichek taught stents comprising genetically modified cells expressing tissue-type plasminogen activator (t-PA) (Circulation, 1989, Vol. 80, pg 1347-1353).

Yuan (Chinese Medical Journal, 2001, Vol. 114, no. 10, pg 1043-1045) coated a metallic stent with adenovirus encoding LacZ immersed in a gelatin solution and a crosslinker.

The art at the time of filing did not teach how to use genetically modified cells encoding an enzyme capable of catabolizing cholesterol and lipids to treat or prevent disease. Nor did the art at the time of filing teach how to use a vector encoding such an enzyme in the absence of genetically modified cells (direct injection of a vector or plasmid) to treat or prevent disease so that one of skill could guess how to use genetically modified cells encoding such and enzyme. Accordingly, it was unpredictable how to target cells of interest using genetically modified cells expressing an enzyme capable of catabolizing cholesterol and lipids to treat or prevent disease.

The specification teaches immobilizing cells on a stent having an underlayer of nitrogen (pg 5-6, Example 1). Example 2 teaches transfecting umbilical vein endothelial cell line with an AAV vector encoding lipoprotein lipase (LPL) and seeding the cells onto a stent.

The specification does not teach where to insert the stent, the amount of LPL expressed, the amount of LPL required to treat or prevent disease or how to target the LPL to the tissues of interest such that disease is treated or prevented. Without such guidance, the specification fails to overcome the unpredictability in the art to use the stent comprising genetically modified cells expressing LPL to treat or prevent disease.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to an intravascular stent comprising an inner surface having genetically modified cells that produce an enzyme capable of catabolizing cholesterol and lipids. Claim 11 is drawn to a method of using the stent to treat or prevent obstructive artheriosclerotic lesions in coronary and peripheral blood vessels, or prevent restenosis in intra coronaric stents.

The phrase enzyme “capable of catabolizing cholesterol and lipids” lacks written description. The phrase is mentioned on pg 4, but the only enzyme disclosed in the specification or the prior art of record that catabolizes cholesterol and lipids is lipoprotein lipase (LPL). Therefore, the claims should be limited to LPL.

The art at the time of filing did not reasonably teach or suggest a stent comprising cells genetically modified to produce an enzyme capable of catabolizing

cholesterol and lipids as claimed. In particular, in vivo or ex vivo LPL gene therapy was not adequately taught or suggested in the art at the time of filing. Accordingly, those of ordinary skill would not have reasonably combined stent technology with cells genetically modified to produce an enzyme capable of catabolizing cholesterol and lipids as claimed.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Patent Examiner